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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/084,638	02/27/2002	Michael Babich	21511/92177	3698

23644 7590 10/07/2009

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ART UNIT	PAPER NUMBER
1644	

NOTIFICATION DATE	DELIVERY MODE
10/07/2009	ELECTRONIC

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte MICHAEL BABICH

Appeal 2009-003335
Application 10/084,638
Technology Center 1600

Decided: October 05, 2009

Before RICHARD M. LEBOVITZ, JEFFREY N. FREDMAN,
and STEPHEN WALSH, *Administrative Patent Judges*.

FREDMAN, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to a diagnostic test for allergies. We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

Statement of the Case

Background

"Profilins are cytoskeletal proteins expressed in all eukaryotic cells that sequester G-actin and bind to membrane-associated phosphatidylinositol-4,5-bisphosphate" (Spec. 1, ll. 13-15). According to the Specification, "[m]ultimers of plant profilin are a preferred form for diagnosis and treatment of allergies" (Spec. 1, ll. 8-9).

The Claims

Claims 17 and 22-28 are on appeal. Independent claim 17 is representative and reads as follows:

> 17. A diagnostic test for allergies, said test comprising:
> (a) obtaining a pharmaceutical composition of multimeric profilin;
> (b) administering the composition to a subject; and
> (c) determining a reaction from which allergenicity is inferred.

The prior art

The Examiner relies on the following prior art references to show unpatentability:

Valenta US 5,583,046 Dec. 10, 1996

Vrtala et al., *Induction of IgE antibodies in mice and rhesus monkeys with recombinant birch pollen allergens: Different allergenicity of Bet v 1 and Bet v 2*, 98 J. ALLERGY CLIN. IMMUNOL 913-921 (1996).

The issue

The Examiner rejected claims 17 and 22-28 under 35 U.S.C. § 102(b) as being anticipated by Valenta as evidenced by Vrtala (Ans. 3-4).

The Examiner finds that Valenta "teaches obtaining and administering the recombinant or synthetic P14 allergen," which is the same as the claimed profilin, in pharmaceutically acceptable carriers, into patients to diagnostically determine allergenicity to said protein (Ans. 3). The Examiner finds that Valenta is "silent as to whether the Bet v2 [profilin] is multimeric" (Ans. 3). The Examiner finds that Vrtala "teaches that Bet v2 naturally polymerizes in solution to form stable polymers" (Ans. 3).

Appellant contends that "[t]here is no teaching in the [Valenta] '046 patent that when Bet v2 is placed in solution, as required to administer to a subject in non-lyophilized form, it polymerizes due to the physical properties of the molecule" (App. Br. 5). Appellant contends that "[t]he form Vrtala injected into the animal models is not clear, but likely is a monomeric form. Conditions to make a soluble form were followed that would produce mostly monomeric profilin" (App. Br. 6).

In view of these conflicting positions, we frame the anticipation issue before us as follows:

Has Appellant demonstrated that the Examiner erred in finding that the profilin of Valenta is inherently multimeric based upon the evidence of Vrtala?

Findings of Fact (FF)

1. Valenta teaches "a method for detecting allergic reactions to a P14 allergen by administering a recombinant P14 of the invention to a subject, so as to provoke a bronchial, conjunctival, dermal, nasal or oral immunological reaction" (Valenta, col. 4, ll. 32-36).

2. The Examiner finds, and Appellant does not dispute, that the Bet v2 P14 allergen of Valenta is identical to the profilin of claim 17 (see Ans. 3).

3. Valenta teaches that the "polypeptides can be administered to a human subject either alone or in combination with pharmaceutically acceptable carriers or diluents, in accordance with standard pharmaceutical practice" (Valenta, col. 11, ll. 36-40).

4. Vrtala teaches that "birch pollen profilin (Bet v 2) induces IgE antibodies in about only 10% to 20% of patients allergic to pollen . . . , showing, however, extensive cross-reactivities with profilins from pollen and food" (Vrtala 913, col. 2).

5. Vrtala teaches that "rBet v 2 migrated as a single band at 14 kd only under reducing conditions. When β-mercaptoethanol was omitted from the sample buffer, additional bands could be stained, of which one migrated at 28 kd" (Vrtala 916, col. 2).

6. Vrtala teaches that "[t]o further investigate whether the higher molecular bands that were observed in the Bet v 2 preparation under nonreducing conditions might be due to formation of polymers through disulfide bonds, immunoblots were done. Two different anti-profilin antisera identified the higher molecular weight bands as Bet v 2 polymers" (Vrtala 916, col. 2).

7. Vrtala teaches that "[i]t is hence suggested that the binding [between labeled and unlabeled Bet v 2] occurs through the formation of disulfide bonds" (Vrtala 916, col. 2).

8. Vrtala teaches that "it is hence possible that the weaker capacity of rBET v 2 to induce IgE antibodies might be linked to the ability of Bet v 2 to form natural polymers through disulfide bonds" (Vrtala 920, col. 1).

Principles of Law

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987). Analysis of whether a claim is patentable over the prior art under 35 U.S.C. § 102 begins with a determination of the scope of the claim. We determine the scope of the claims in patent applications not solely on the basis of the claim language, but upon giving claims their broadest reasonable construction in light of the specification as it would be interpreted by one of ordinary skill in the art. *In re Am. Acad. of Sci. Tech. Ctr.*, 367 F.3d 1359, 1364 (Fed. Cir. 2004). The properly interpreted claim must then be compared with the prior art.

"[A] prima facie case of anticipation [may be] based on inherency." *In re King*, 801 F.2d 1324, 1327 (Fed. Cir. 1986). Once a prima facie case of anticipation has been established, the burden shifts to the Appellant to prove that the prior art product does not necessarily or inherently possess the characteristics of the claimed product. *In re Best*, 562 F.2d 1252, 1255 (CCPA 1977) ("Where, as here, the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the

characteristics of his claimed product."). *See also In re Spada*, 911 F.2d 705, 708-09 (Fed. Cir. 1990).

Analysis

Valenta teaches a diagnostic test for allergies comprising obtaining a pharmaceutical composition of a P14 profilin (FF 3), administering the P14 profilin to a subject and determining an allergic reaction (FF 1). The P14 profilin of Valenta is identical to the Bet v2 antigen (FF 2).

While Valenta does not teach that P14 profilin (Bet v2) is multimeric, the Examiner relies upon Vrtala to demonstrate that in solution, Bet v2 is inherently multimeric (FF 4-8). Vrtala expressly demonstrates the presence of both the 14 kd monomeric band and the 28 kd multimeric (dimeric) band and shows that the 28 kd band is reactive to antibodies to Bet v2 (FF 5-6)

We agree with the Examiner that Vrtala demonstrates the Bet v2 in solution forms a composition composed of both monomers and multimers (FF 4-8).

We are not persuaded by Appellant's argument that the "examiner has not demonstrated recognition of multimeric profilin as a hyposensitizing agent" (App. Br. 3). As we find above, Valenta expressly teaches the use of profilin as a hyposensitizing agent and Vrtala demonstrates that when profilin is in solution, profilin is multimeric (FF 1-8). In *Schering,* the Federal Circuit noted that "this court rejects the contention that inherent anticipation requires recognition in the prior art." *Schering Corp. v. Geneva Pharm., Inc.*, 339 F.3d 1373, 1377 (Fed.Cir.2003). *Schering* also commented that "[o]ther precedents of this court have held that inherent anticipation does not require that a person of ordinary skill in the art at the

time would have recognized the inherent disclosure. E.g., In re Cruciferous Sprout Litig., 301 F.3d 1343, 1351 (Fed.Cir.2002)." *Id. Also see MEHL/Biophile Int'l Corp. v. Milgraum*, 192 F.3d 1362, 1366 (Fed.Cir.1999) ("Where ... the result is a necessary consequence of what was deliberately intended, it is of no import that the article's authors did not appreciate the results.")

We are not persuaded by Appellant's argument that "there is no justification for adding Vrtala to what should be a rejection based on a single case." The use of additional references to evidence that a reference inherently satisfies the claims is permitted. *See In re Samour*, 571 F.2d 559, 563 (CCPA 1978) ("Additional references cited in a rejection under 35 U.S.C. § 102(b) are not relied on for a suggestion or incentive to combine teachings to meet claim limitations (as in a rejection under 35 U.S.C. s 103), but, rather, to show that the claimed subject matter, every material element of which is disclosed in the primary reference, was in possession of the public.").

We are not persuaded by Appellant's argument that "[a]s the examiner admits, the '046 patent does not disclose all the claim elements" (App. Br. 4). The element missing from Valenta (the '046 patent) is the inherent fact that P14 (Bet v2) is multimeric in solution. The Examiner provides specific and credible evidence, which is not rebutted by Appellant, that Bet v2 is multimeric in solution (FF 4-8). "It is well settled that a prior art reference may anticipate when the claim limitations not expressly found in that reference are nonetheless inherent in it." *In re Cruciferous Sprout Litigation*, 301 F.3d 1343, 1349 (Fed. Cir. 2002). See, e.g., *MEHL/Biophile*

Int'l Corp. v. Milgraum, 192 F.3d 1362, 1365 (Fed.Cir.1999) ("Under the principles of inherency, if the prior art necessarily functions in accordance with, or includes, the claimed limitations, it anticipates.")

We are not persuaded by Appellant's argument that the "form Vrtala injected into the animal models is not clear, but likely is a monomeric form" (App. Br. 6). Appellant also argues that "[p]roduction of a monomeric form . . . for injection is consistent with the production in animal models of monomeric-recognizing IgG and IgE (lesser degree) shown in Figure 3. Indeed, there were no noted antibodies that recognized the larger profilin forms" (App. Br. 6).

Valenta expressly teaches the use of profilin as a hyposensitizing agent in a solution (FF 1-3). Vrtala demonstrates that when profilin is in solution, profilin is multimeric (FF 4-8). Appellant has provided no evidence to rebut Vrtala's showing of "the ability of Bet v 2 to form natural polymers through disulfide bonds" (Vrtala 920, col. 1). This provides evidentiary support that profilin will inherently form natural polymers in solution, as used by Valenta. Further, Vrtala expressly teaches "[t]wo different anti-profilin antisera identified the higher molecular weight bands as Bet v 2 polymers" (Vrtala 916, col. 2; FF 6), which rebuts Appellant's argument that "there were no noted antibodies that recognized larger profilin forms" (App Br. 6). Vrtala expressly suggests that "the decreased allergencity of rBet v 2 might be related to its tendency to polymerize" (Vrtala 914, col. 1), which teaches that Vrtala expects that the rBet v 2 forms polymers in solution.

We are not persuaded by Appellant's argument that "Vrtala teaches against the present invention" (App. Br. 5). Appellant argues that "[t]he utility of profilin polymers was not recognized nor was it obvious that the profilin polymers would be a key allergen" (App. Br. 7).

The rejection at issue is under 35 U.S.C. § 102(b), as anticipated by Valenta, and is not an obviousness rejection. Vrtala is relied upon by the Examiner solely to evidence the inherent fact that Bet v2 is multimeric in solution, in order to demonstrate that Valenta inherently anticipates the claims. Therefore, we find that Appellant's "teaching away" argument misplaced because the Examiner has rejected the claims under 35 U.S.C. § 102. Our reviewing court has determined that "[t]eaching away is irrelevant to anticipation." *Seachange International, Inc., v. C-Cor, Inc.*, 413 F.3d 1361, 1380 (Fed. Cir. 2005).

Conclusion of Law

Appellant has not demonstrated that the Examiner erred in finding that the profilin of Valenta is inherently multimeric based upon the evidence of Vrtala.

SUMMARY

In summary, we affirm the rejection of claim 17 under 35 U.S.C. § 102(b) as anticipated by Valenta as evidenced by Vrtala. Pursuant to 37 C.F.R. § 41.37(c)(1)(vii)(2006), we also affirm the rejection of claims 22-28 as these claims were not argued separately.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1)(iv)(2006).

AFFIRMED

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